



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,327	04/12/2001	Samuel J. Danishefsky	2003080-0081(SK-719-Z)	3477

24280 7590 06/17/2003

Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/833,327

Applicant(s)
Danishefsky et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108, 110-114, and 116-118 is/are pending in the application.
- 4a) Of the above, claim(s) 112 and 113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 108, 110, 111, 114, and 116-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1642

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 108, 110, 111, 114 and 116-118 have been amended. Claims 109 and 115 have been canceled. Claims 112 and 113 remain withdrawn from consideration. Claims 108, 110, 111, 114 and 116-118 are under consideration.
3. The amendment filed July 9, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:
 - (A) the structure on the bottom of page 2 of 19, and the structure at the top of page 4 of 19 wherein the index number "n" was added to the last sugar moiety. It is noted that the specification as filed has only index numbers "r" and "m", on pages 48 and 58 although the amendment indicates that the structure which was being replaced had index numbers "r", "m" and "n";
 - (B) the structure referred to in section 3 of page 19 which replaces a sugar moiety having an acetylated hydroxyl group with a sugar moiety not having an acetylated hydroxyl group;
 - (C) the structure referred to in section 4 of page 4 of 19 which replaces a structure carrying a t-butyl group with an open-ended bond, and also replaces a sugar moiety having a benzoyl group with a sugar moiety not having said benzoyl group;
 - (D) the structure referred to in section 6 of page 5 of 19 which replaces three sugar moieties carrying benzoyl groups with three sugar moieties not carrying benzoyl groups;

Applicant is required to cancel the new matter in the reply to this Office Action.

Art Unit: 1642

4. Claims 108, 110, 111, 114, 116-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 108, 110, 114 and 116 have been amended to incorporate the limitation "when R is a ceramide moiety, the set of indices (r, m, n) is not (1, 0, 1). Neither the specification or claims as filed provides support for this negative limitation. It is noted that the specification Further, the limitation of having three index numbers (r, m and n) is new matter as the specification as filed contemplates only the two index numbers of "r" and "m" for the reasons set forth in the objections to the specification above. It is noted that the specification specifically contemplates the nona-saccharide ceramide which has been excluded by the amendments (page 58).

5. All other rejections and objections as set forth in Paper No. 9 are withdrawn.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

June 16, 2003